K021092

MAY 16 2002

**Philips Lighting Company**

## 510K SUMMARY STATEMENT


Company Name: Philips Lighting Company
200 Franklin Square Drive
Somerset, NJ 08875-6800

Contact: Toni J. Hoffmann
Corporate Quality Analyst

Telephone: 732-563-3081


Trade Names: **Philips TL20W/01/RS UV-B**
**Philips PL-S 9W/01/2P UV-B**
**Philips PL-L 36W/01/4P UV-B**

**Common Name:** **UVB Lamps**

**Classification: Light, Ultraviolet, Dermatological**

**Description:**
**Philips TL20W/01/RS UV-B**
**Watts - 20**
**Volts - 57**
**Base - G13**
**Bulb - T12**
**Length - max 604mm pin end to pin end**
**Philips PL-S 9W/01/2P UV-B**
**Watts - 9**
**Volts - 60**
**Base - G23**
**Length - max OAL - 167 mm**
**Philips PL-L 36W/01/4P UV-B**
**Watts - 36**
**Volts - 105**
**Base - 2G11**
**Length - max OAL - 417 mm**

**Intended Use:** **The intended function of the UV-B ultraviolet lamp is therapy for Psoriasis and Vitiligo.**

**Equivalence:** **Substantial equivalence previous devices. Lamps are different dimensionally but have substantially equivalent outputs to Philips TL100W/01 UV-B**

**Ref: FDA-510K Summary Statement**
**File: 14.01.23**

ISO 9001 KEMA CERT

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 6 2002

Ms. Toni Hoffmann
Corporate Quality Analyst
Philips Lighting Company
200 Franklin Square Drive
Somerset, NJ 08875-6800

Re: K021092
Trade/Device Name: Philips TL20W/01/RS UV-B
Philips PL-S 9W/01/2P UV-B
Philips PL-L 36W/01/4P UV-B
Regulation Number: 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: FTC
Dated: March 7, 2002
Received: April 4, 2002

Dear Ms. Hoffman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PHILIPS

**Philips Lighting Company**

# INDICATION FOR USE STATEMENT

510(k) Number (if known): K021092

Device Names: Philips TL20W/01/RS UV-B
Philips PL-S 9W/01/2P UV-B
Philips PL-L 36W/01/4P UV-B

The intended function of the UV-B ultraviolet lamp is therapy for Psoriasis and Vitiligo.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of DCRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021092

Prescription Use X
(Per 21 CRF 8001.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)



A division of
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